

R<sub>1</sub>-X-Glu-Gly-Thr-Phe-Thr-Ser-Asp-Val-Ser-  
Ser-Tyr-Leu-Y-Gly-Gln-Ala-Ala-Lys-Z-Phe-  
Ile-Ala-Trp-Leu-Val-Lys-Gly-Arg-R<sub>2</sub>  
(SEQ ID NO:1)

wherein:

R<sub>1</sub> is histidine;

X is Gly, Val, Thr, Ile, or alpha-methyl-Ala;

Y and Z are each Glu; and

R<sub>2</sub> is NH<sub>2</sub> or Gly-OH;

said method comprising the step of [,]  
administering an effective amount of [a] the GLP-1  
molecule, or a pharmaceutically-acceptable salt of the  
GLP-1 molecule, [selected from the group consisting of  
GLP-1, GLP-1 analogs, or GLP-1 derivatives] to a  
patient in need thereof by pulmonary means.

2. The method of **Claim 1**, wherein the GLP-1 molecule is delivered to lower airway[al]s of the patient.

18. A method of administering [The method of Claim 17,  
wherein the GLP-1 analog is selected from the group  
consisting of] Val<sup>8</sup>-GLP-1(7-37)OH, Gly<sup>8</sup>-GLP-1(7-37)OH  
or [and] Asp<sup>8</sup>-GLP-1(7-37)OH, comprising administering  
an effective amount of Val<sup>8</sup>-GLP-1(7-37)OH, Gly<sup>8</sup>-GLP-  
1(7-37)OH or Asp<sup>8</sup>-GLP-1(7-37)OH or a pharmaceutically  
acceptable salt thereof, to a patient in need thereof  
by pulmonary means.

19. A method of administering [The method of Claim 18,  
wherein the GLP-1 analog is] Val<sup>8</sup>-GLP-1(7-37)OH,  
comprising administering an effective amount of Val<sup>8</sup>-  
GLP-1(7-37)OH, or a pharmaceutically acceptable salt of  
Val<sup>8</sup>-GLP-1(7-37)OH, to a patient in need thereof by  
pulmonary means.

21. A method for treating a patient with diabetes,  
comprising[, ] administering an effective dose of a GLP-  
1 molecule, or a pharmaceutically acceptable salt of  
the GLP-1 molecule, to [a] the patient [in need  
thereof] by pulmonary [delivery] means, said GLP-1  
molecule having the amino acid sequence of SEQ ID NO:  
1:

R<sub>1</sub>-X-Glu-Gly-Thr-Phe-Thr-Ser-Asp-Val-Ser-  
Ser-Tyr-Leu-Y-Gly-Gln-Ala-Ala-Lys-Z-Phe-  
Ile-Ala-Trp-Leu-Val-Lys-Gly-Arg-R<sub>2</sub>  
(SEQ ID NO:1)

wherein:

R<sub>1</sub> is histidine;

X is Gly, Val, Thr, Ile, or alpha-methyl-Ala;

Y and Z are each Glu; and

R<sub>2</sub> is NH<sub>2</sub> or Gly-OH.

23. A method for treating a patient with diabetes,  
comprising administering an effective dose of [The

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conclude

method of Claim 21, wherein the GLP-1 molecule is] Val<sup>8</sup>-GLP-1(7-37)OH or a pharmaceutically effective salt of Val<sup>8</sup>-GLP-1(7-37)OH, to the patient by pulmonary means.

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31. A method for treating a patient with hyperglycemia comprising, administering an effective dose of a GLP-1 molecule, or a pharmaceutically acceptable salt of the GLP-1 molecule, to [a] the patient [in need thereof] by pulmonary means, said GLP-1 molecule having the amino acid sequence of SEQ ID NO: 1:

R<sub>1</sub>-X-Glu-Gly-Thr-Phe-Thr-Ser-Asp-Val-Ser-  
Ser-Tyr-Leu-Y-Gly-Gln-Ala-Ala-Lys-Z-Phe-  
Ile-Ala-Trp-Leu-Val-Lys-Gly-Arg-R<sub>2</sub>  
(SEQ ID NO:1)

wherein:

R<sub>1</sub> is histidine;

X is Gly, Val, Thr, Ile, or alpha-methyl-Ala;

Y and Z are each Glu; and

R<sub>2</sub> is NH<sub>2</sub> or Gly-OH.

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33. A method for treating a patient with hyperglycemia, comprising administering an effective dose of [The method of Claim 31, wherein the GLP-1 molecule is] Val<sup>8</sup>-GLP-1(7-37)OH, or a pharmaceutically acceptable salt of Val<sup>8</sup>-GLP-1(7-37)OH, to the patient by pulmonary means.

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41. A method of administering a glucagon-like peptide-1(GLP-1) molecule, said method comprising the step of

administering an effective amount of the GLP-1 molecule, or a pharmaceutically acceptable salt of the GLP-1 molecule, to a patient in need thereof by pulmonary means, wherein said GLP-1 molecule has the amino acid sequence of GLP-1(7-34)OH, GLP-1(7-34)NH<sub>2</sub>, GLP-1(7-35)OH, GLP-1(7-35)NH<sub>2</sub>, GLP-1(7-36)OH, GLP-1(7-36)NH<sub>2</sub>, GLP-1(7-37)OH or GLP-1(7-37)NH<sub>2</sub>, modified by replacing alanine at position 8 with an amino acid having an uncharged side chain.

42. A method for treating a patient with diabetes, comprising administering an effective dose of a GLP-1 molecule, or a pharmaceutically effective salt of the GLP-1 molecule, to the patient by pulmonary means, wherein said GLP-1 molecule has the amino acid sequence of GLP-1(7-34)OH, GLP-1(7-34)NH<sub>2</sub>, GLP-1(7-35)OH, GLP-1(7-35)NH<sub>2</sub>, GLP-1(7-36)OH, GLP-1(7-36)NH<sub>2</sub>, GLP-1(7-37)OH or GLP-1(7-37)NH<sub>2</sub>, modified by replacing alanine at position 8 with an amino acid having an uncharged side chain or the amide form thereof.

43. A method for treating a patient with hyperglycemia, comprising administering an effective dose of a GLP-1 molecule, or a pharmaceutically acceptable salt of the GLP-1 molecule, to the patient by pulmonary means, wherein said GLP-1 molecule has the amino acid sequence of GLP-1(7-34)OH, GLP-1(7-34)NH<sub>2</sub>, GLP-1(7-35)OH, GLP-1(7-35)NH<sub>2</sub>, GLP-1(7-36)OH, GLP-1(7-36)NH<sub>2</sub>, GLP-1(7-37)OH or GLP-1(7-37)NH<sub>2</sub>, modified by replacing alanine at position 8 with an amino acid residue having an uncharged side chain or the amide form thereof.

#### REMARKS

##### Telephonic Interview

Examiner Lukton is thanked for granting the telephonic interview and for his helpful comments during the interview. It was agreed during the interview that the Examiner would